

REMARKS

Upon entry of the present Amendment, claim 29 has been added, and claims 1, 3, 4, 6-8, 13, 15 and 17-29 are pending.

The Present Invention

The method of the present invention is directed to a method of treating or preventing specific bacterial infections in animals by feeding the animals a feed containing xylanase (claim 1) or a cellulase (claim 21) enzyme. As indicated in the specification at page 7, lines 11-19,

"The advantage of using feeds containing a xylanase or a cellulase for rearing animals is that the amount of antimicrobial drugs which have previously been routinely incorporated into their diet can be reduced, or in some cases omitted entirely. This enables considerable economic savings to be achieved in view of the relative expense of antibiotics. In countries where such drugs are banned, it represents a totally new approach to the control of bacterial diseases."

Further, the present invention provides the following additional advantages:

- The animal can be slaughtered at any age rather than after a certain withdrawal period.
- The removal of antibiotics from feeds reduces the selection pressures that can generate antibiotic resistant strains

Claim 29 has been added to more specifically claim the use of  $\beta$ -glucanase in combination with wheat.

Rejections of Claims under 35 USC 102

None of the cited references describe a method for treating or preventing infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens* in animals as

claimed. The cited references merely teach that xylanase can be used as a feed additive to assist in digestion. Hence, the advantages of using the present invention are not taught or suggested by the cited references.

GB 2287867: The '867 reference does not disclose or teach a method for treating or preventing a bacterial infection in an animal as claimed. The '867 reference merely describes a method of using enzymes to assist an animal in the digestion of proteins in the form of a food additive. More specifically, the '867 reference makes no suggestion that feeding an animal either xylanase (claim 1) or cellulase (claim 21) would have any effect whatsoever on infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens*. The '867 reference does not even mention any infectious bacterial agents. Hence, persons of ordinary skill would not recognize that such enzymes are necessarily effective in treating or preventing a bacterial infection of any kind. In order to serve as an anticipation when the reference is silent regarding the asserted inherent characteristic, there must be evidence that makes it clear that the missing descriptive matter is necessarily present in the thing described and that it would be so appreciated or recognized by persons of ordinary skill that the characteristic would be present. See Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). See also Glaxo, Inc. v. Novopharm, Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995). In the present case, it would not be appreciated by or expected by those of ordinary skill that the enzymes disclosed in the '867 reference would be effective in treating any kind of bacterial infection, as feed producers have routinely and commonly added antibiotics to their feed in order to prevent and treat bacterial infections.

*Salmonella  
well  
known  
in  
diseases*

U.S. Patent No. 5,612,055: The '055 patent is directed to an enzyme feed additive and does not describe or suggest a method for preventing infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens* in animals as claimed. Infectious bacterial agents are not even mentioned in the '055 patent.

The object of the '055 patent is to provide an enzyme feed additive for improving the feed conversion ratio and/or increasing the digestibility of a cereal-based feed, see column 7, lines 10-13,. The case law of what is necessary to show anticipation of an invention by a prior art document discussed above in relation to the '867 reference above is therefore equally applicable to the '055 patent. *Same*

U.S. Patent No. 5,902,581: The '581 patent describes xylanase enzymes for use in the bleaching of pulp for paper production and for use in feed compositions as a digestive aid. The '581 reference does not describe or suggest a method for treating or preventing bacterial infections in animals as claimed. The '581 reference teaches how the feed containing the enzymes is to be produced free from harmful bacteria through heating, see col. 3, lines 1-5, or through the application of heat and pressure in an expander, see col. 3, lines 36-41. It does not teach that the xylanase itself would have any effect whatsoever on the harmful bacteria, either in the feed or an animal. Therefore, the '581 reference merely discloses a method to produce a feed initially free from harmful bacteria and the use xylanase as a digestive aid in food. It does not disclose or suggest a method of using enzymes for treating or preventing infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens* in an animal as claimed. ~~X~~

U.S. Patent No. 5,817,500: The '500 patent is directed to an enzyme feed additive and does not describe or suggest a method for preventing infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens* in animals as claimed. The '500 reference merely discloses that certain thermostable xylanases may be processed into feed additives using conditions that prevent microbial infections in the feed itself, due to their increased thermostability, by processing them at elevated temperatures, see col.2, lines 2-6 and lines 11-17. The '500 reference discloses nothing regarding a method for preventing or treating infections caused by ~~bacteria~~ in an animal or in the feed.

Rejection of claims under 35 USC 103

A method for treating or preventing specific types of bacterial infections in animals using xylanase or cellulase as claimed is not described or suggested in any of the cited references either alone or in combination.

GB '867 in view of US '055: The combination of GB '867 and the '055 patent does not describe or suggest a method for treating or preventing bacterial infections in an animal as claimed. The cited references together describe the addition of enzymes to animal feed, but make no suggestion that such an addition would have any effect other than to facilitate the digestion of food by the animal. The mere fact that the feed additives have been given to chickens and chickens are known to suffer from *Salmonella* infections would not lead one of ordinary skill to believe that such an additive would have any effect on such an infection. One of ordinary skill would not have a reasonable expectation based on these references that addition of xylanase or cellulase to a feed would be effective in treating or preventing infections caused by *Salmonella*,

*Campylobacter* or *Clostridium perfringens* in animals as claimed.

The only suggestion that the method of the present invention would be useful against bacterial infections is provided in the Applicant's own specification. Such suggestion must be present in the prior art to render a claimed invention obvious.

U.S. '581 in view of US '055: The combination of the '581 patent and the '055 patent describes the use of enzymes for treating food or as a food additive that assists in digestion but does not describe or suggest a method for treating or preventing bacterial infections caused by specific bacteria as claimed. The combination of these references teaches that xylanase can be produced as a food additive in such a way that it is initially free from harmful bacteria, but teaches nothing regarding the use of xylanase in treating or preventing bacterial infections. The combination of these references would not teach one of ordinary skill that xylanase or cellulase additions to feeds would be effective in preventing or treating bacterial infections. The combination of these references would require that one of ordinary skill undertake undue experimentation to determine if these enzyme additions to feed would be effective in preventing or treating bacterial infections and, if so, if these enzyme additions would work with the specific bacteria as claimed.

U.S. '500 in view of GB '867: The '500 patent and GB '867 references teach the use of enzymes as a feed additive to aid in digestion, but make no mention of the use of these enzymes in a method for treating bacterial infections caused by specific bacteria as claimed. The references state that the feed additives can be produced free from harmful bacteria due

to the increased thermostability of the enzyme, but do not teach that the enzyme itself has any effect whatsoever on the harmful bacteria, either in the feed or in the animal. The combination of these references would not teach or suggest that enzyme addition to a feed would be effective in treating or preventing infections caused by *Salmonella*, *Campylobacter* or *Clostridium perfringens* in animals as claimed.

Conclusion

In view of the remarks made herein, Applicants respectfully request allowance of the pending claims.

The Commissioner is hereby authorized to charge any additional fees which may be required in this application to Deposit Account No. 06-1135.

Respectfully submitted,

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